NMA

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Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

FAX: 301-827-6870

Re: Docket No. 2002N-0273
Federal Register Vol. 70 No. 193
Thursday, October 6, 2005 Proposed Rule:
Substances Prohibited From Use in Animal
Food or Feed

Gentlemen:

National Meat Association, organized in 1946, represents the interests of meat packers and processors throughout the United States. Close to 300 general member companies, about 25% of whom are meat slaughters and several of these having more than one slaughter facility, have a substantial interest in the Proposed Rule. On behalf of NMA members we respectfully submit the following comments in response to the Food and Drug Administration request regarding the *Federal Register* Proposed Rule entitled "Substances Prohibited From Use in Animal Food and Feed".

NMA recognized and supported the needs for APHIS to impose safeguards as early as 1989 to prevent BSE from entering the United States. We also supported the efforts of FDA in 1997 with the issuance of the Final Rule prohibiting the use of mammalian protein in ruminant feed in order to prevent the introduction of Bovine Spongiform Encephalopathy (BSE) in the United States. The final rule also established regulatory requirements for persons who manufacture, process, blend or distribute animal protein products in order to ensure that ruminant feed did not contain protein from a mammalian source. In 2004, NMA was supportive of FSIS efforts to minimize the risks posed by BSE by requiring that plants develop procedures in their food safety programs to identify, segregate and divert all "Specified Risk Materials" from incorporation into human and/or ruminant animal food chain. NMA again fully supported the efforts of APHIS in conducting BSE surveillance programs to test animals at risk and cooperated in enlisting plants to participate in the latest 20,000 healthy animals testing program. These testing programs serve as verification for the implementation and execution of government and industry programs aimed at minimizing the risks of BSE in the United States.

The October 6, 2005 *Federal Register* publication entitled "Substances Prohibited From Use in Animal Food or Feed; Proposed Rule" proposes restrictions in addition to the

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existing ruminant feed rule. Specifically the proposed rule will prohibit the following "high risk" materials from all animal feed as a means of strengthening existing safeguards to prevent the spread of BSE in the U.S.

- Brains and spinal cords of cattle 30 months of age or older
- Brains and spinal cord of cattle not inspected and passed for human consumption regardless of age
- The entire carcass of cattle not inspected and passed if brains and spinal cord are not removed regardless of age
- Tallow derived from any of the aforementioned unless tallow contained no more than 0.15 percent insoluble impurities
- Mechanically separated beef derived from any of the prohibited above-named materials

The proposed rule would also require that renderers that handle "Cattle Materials Prohibited in Animal Feed" (CMPAF) utilize separate equipment or containers to prevent cross contamination of other materials intended for animal feed. In addition to labeling and marking procedures to identify high-risk materials, the proposed rule requires renderers to establish and maintain record-keeping systems in order to demonstrate that materials rendered for use in animal feed are not manufactured from or processed with CMPAF and make these records accessible for review and investigative purposes.

The proposed rule explains that there is a need for further requirements because private suppliers and purchasers in markets for cattle rendering and ruminant feed may inadequately address the risk of BSE that is implied to be inherent in the feed that they are handling. It goes on to state that this is a result of inadequate information being available to buyers of potentially infective animal feed, which implies that labeling would alleviate this problem. And lastly the proposed rule would decrease risk of BSE transmission due to cross contamination issues which may result on farms, buyers of ruminant and non-ruminant feed, inadvertently feeding CMPAF to ruminants. NMA agrees that these potential concerns are best addressed through the enhancements contained in the proposed regulation.

However although NMA believes that the proposed rule will provide additional precautionary safeguards we are providing the following comments and requesting that the following issues be further clarified within the scope of the new rule.

1. Brains and spinal cord are identified in the FSIS interim final rule as SRMs only in cattle 30 months and older and are required to be addressed in each official establishment's operating procedures. Specifically the procedures are to address the identification, sanitary removal of and segregation and disposal of SRMs. The

issue arises when the proposed rule classifies brains and spinal cord as prohibited material when cattle are "not inspected and passed". Live cattle or carcasses may be identified as "not inspected and passed" at *ante mortem* inspection or *post mortem* inspection. If live cattle are not inspected and passed at *ante mortem* inspection, risk materials may be easily segregated at that time. However, if "not inspected and passed" applies to *post mortem* inspection at the final rail, the brains and spinal cord of cattle have at that time been removed and placed into commingled inedible rendering, thus creating a situation where all of the inedible material from the start of operations would have to be regarded as prohibited material and disposed of accordingly. It is therefore critical that the rule provides clarification as to what point will "not inspected and passed" be applicable. We strongly recommend that the language only apply to *ante-mortem* inspection given that is where suspect animals are identified and segregated. The most common reasons for condemnation at *post-mortem* inspection have no relevance to BSE control.

2. NMA has concerns with agency oversight regarding enforcement jurisdiction. It is quite clear that FSIS provides oversight activities with regards to ensuring that SRMs do not enter the human food chain. The prohibition of CMPAF is clearly the responsibility of FDA with regards to animal feed. Given this, we strongly recommend that no new FSIS inspectional activity be adopted for this regulation.

As we previously stated, NMA supported the efforts of FDA, FSIS and APHIS in their endeavors to take meaningful steps based upon scientific data and epidemiological conclusions. NMA recognizes the basis for these additional proposed precautionary measures and understands that the benefits will effectively remove about 90 percent of any remaining potential infectivity from possible spread of any potential infectious BSE agent through the feed system.

We believe that it is essential that rules be promulgated based on the best available scientific data. This proposed rule, while it makes logical arguments to support its promulgation, lacks clear scientific data to support its final issuance. We believe that it is imperative that such data be provided to support a final rule. Further, we agree with the National Renderers Association that, absent the development of alternate methods of disposal of SRMs, meat packers will be facing major increases in disposal costs, and this cost must be calculated and presented in any final rule.

We appreciate the opportunity to comment on the proposed rule and hope that our comments and suggestion will be taken into consideration.

Sincerely,

Rosemary Mucklow
Executive Director

Ken Mastracchio
Associate Director